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09/474,435	12/28/1999	Yongwei Cao	16517.044/15473B	2233
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			SALMON, KATHERINE D	
WASHINGTON, DC 20004			ART UNIT	PAPER NUMBER
			1634	
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			08/04/2009	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

	Application No.	Applicant(s)				
	09/474,435	CAO ET AL.				
Office Action Summary	Examiner	Art Unit				
	KATHERINE SALMON	1634				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>02 Ar</u>	pril 2009.					
	action is non-final.					
3) Since this application is in condition for allowan						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>2,6,12-14,19-21,26 and 60-78</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>2,6,12-14,19-21,26 and 60-78</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
<ul><li>1. Certified copies of the priority documents have been received.</li><li>2. Certified copies of the priority documents have been received in Application No</li></ul>						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
	,					
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P					
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	6) Other:	aton Application				

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### **DETAILED ACTION**

1. This action is in response to papers filed 4/02/2009.

- 2. Currently Claims 2, 6, 12-14, 19-21, 26, 60-78 are pending. Claims 1, 3-5, 7-11, 15-18, 22-25, and 27-59 have been cancelled.
- 3. The following rejections are newly applied as necessitated by amendment or reiterated. Response to arguments follows.
- 4. This action is being made nonfinal as the rejection for Claim 64 was not set forth in the previous office action of 10/03/2008.

### Withdrawn Rejections

- 5. The rejection of the claims under 35 USC 112/112 2nd made in section 9 of the previous office is most based upon arguments presented in the reply.
- 6. The rejection of the claims under 35 USC 102 made in sections 11-12 of the previous office action is most based upon the amendments to the claims.

# **Priority**

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

7. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

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application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/114151 filed 12/29/1998; 60/120644 filed 2/18/1999; 60/135825 filed 5/24/1999; 60/139932 filed 6/21/1999; 60/143994 filed 7/15/1999; 09/459109 12/13/1999; 60/111990 12/14; 09/459110 12/13/1999; and 60/111991 12/14/1998, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In the preliminary Amendment filed 4/30/2001 amended the instant specification to provide priority to the above application numbers. After a review of the prior applications, it does not appear that the instant claims have support in the above priority applications. The sequence identifiers in each case do not seem to correspond to the sequence identifiers in the instant case and therefore it does not seem that the prior filed applications have support for SEQ ID NO. 5272. For example, Application 60/114151 does not contain a SEQ ID No. 5272 and Application 60/135825 and 60/120644 both contain SEQ ID NO. 5272, but these sequences are not the same as the instantly claimed. In order to obtain priority of the prior filed applications, applicant is requested to disclose the specific sequence identifiers in each prior filed application which is identical to SEQ ID NO. 5272 of the instant application.

### **Response to Arguments**

The reply does not traverse the denial of priority to 60/155422. Therefore the priority is given to application 60/155422 and therefore the priority date is 9/23/1999. This priority was acknowledged on p. 8 of the remarks made in an amendment 8/21/2008.

## Specification

8. The disclosure is objected to because of the following informalities: On p. 1 of the instant specification there is a list of priority under 35 USC 119(e) of a number of US applications which have been denied priority as discussed in the priority section above. The specification should be amended to reflect the proper priority.

Appropriate correction is required.

9. The amendment filed 4/02/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the specification length limitations as recited in US Patent No. 5608144, 4563417, 60/111990, 09/459109, and 09/459110.

The reply asserts that all of these applications were incorporated by reference in their entireties at the time of filing (p. 12 2<sup>nd</sup> paragraph).

After review of the instant specification, it is noted that 09/459109 and 09/459110 have only been disclosed in the 1<sup>st</sup> paragraph with regard to priority. It is noted that as

discussed in the priority section above, the priority to these applications were denied. Therefore there is no language in the specification which specifically "incorporates by reference".

With regard to application 60/111990, the instant specification on p. 37 lines 10-13 disclosed that "The genomic traces and many of the contigs and singleton traces are disclosed in copending provisional applications for patent identified by serial nos....60111990". Therefore there is no language in the specification which specifically "incorporates by reference".

With regard to US Patent number 5608144, the instant specification on p. 19 lines 9-10 "additional promoters that may be utilized are described, for example, in US patent Nos. ...5608144...all of which are herein incorporated in their entirety".

With regard to US Patent NO. 4563417, the examiner could not find any evidence of such a reference in the instant application. Therefore there is no language in the specification which specifically "incorporates by reference".

After review of MPEP 608.01(p) [R-3] the mere recitation of these patent applications have not been found sufficient to amend the specification to particular length limitation embodiments.

MPEP states "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). >37 CFR 1.57(b)(1) limits a proper incorporation by reference (except as provided in 37 CFR 1.57(a)) to instances only where the perfecting words "incorporated by reference" or the root of the words "incorporate" (e.g., incorporating, incorporated) and "reference" (e.g., referencing) appear. The requirement for specific root words will bring greater clarity to the record and provide a bright line test as to where something is being referred to is an incorporation by reference. The Office intends to treat references to documents that do not meet this "bright line" test as noncompliant incorporations by reference and may require correction pursuant to 37 CFR 1.57(g). If a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended. application, the referencing application \*>must< include an identification of the referenced patent, application, or publication. >See 37 CFR 1.57(b)(2)< Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

Guidelines for situations where applicant is permitted to fill in a number for Application No. \_\_\_\_\_\_left blank in the application as filed can be found in In re Fouche, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See >37 CFR 1.14(a)(i)(iv) and (vi) and < MPEP § 103)."

Herein in the instant case, not all the claimed patent application numbers were "incorporated by reference". Further, for the identification of the referenced patent, application, or publication, particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Particularly in the instant case, none of the cited patent applications are found in the section of the instant specification with regard to length limitations. As such the attempt to incorporate particular passages from these patent application and patent documents has been considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

### Claim Rejections - 35 USC § 112/New Matter

10. Claims 2, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Based upon the denial of the amendment to the specification provided above, the limitations in the claims with regard to at least 100 contiguous nucleotide residues, at least 100 contiguous nucleotide residues, and at least about 500 contiguous nucleotide residues have been considered new matter. As the reply to argument specifically claim

that these amendments are found in the specification of US patent No. 5608144, 4563517, US Patent application numbers 60/111990, 09459109, and 09459110, these amendments have not been taught in the specification filed 12/28/1999. As stated above, the amendment to the specification (4/02/2009) is considered new matter and as such the amendments to the claims are rejected under 35 USC 112/New Matter.

# Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

The 35 USC 101 and 35 USC 112/First paragraph set forth below is a reiteration of the rejection set forth in the final rejection mailed 3/18/2008, response to arguments follows.

11. Claims 22, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Claims 2, 6, 12-14, 19-21, 26, 60-78 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to a substantially purified nucleic acid molecules having the sequence of SEQ ID No. 5272, substantially purified nucleic acid molecules comprising fragments of about 100 to 300 nucleotides of SEQ ID No. 5272 and to substantially purified nucleic acid comprising a nucleic acid sequence having at least 98% identity to SEQ ID NO. 5272.

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The claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acid contig and singleton sequences consisting of SEQ ID Nos 1 to 81,306 were isolated from a library prepared from Arabidopsis thaliana ecotype Landsberg erecta tissue (p. 3 lines 17-25 and Example 1). The present claims are limited to nucleic acid comprising SEQ ID NO. 5272 or fragments of SEQ ID NO. 5272 having 98 or 100% identity with SEQ ID No. 5272. The specification does not state whether nucleic acid molecule of SEQ ID NO. 5272 constitutes a complete open reading frame and does not identify the location of the start and stop codons.

The specification also does not set forth a particular biological activity of SEQ ID No. 5272 nor does it describe any protein encoded by SEQ ID No. 5272. Therefore the specification has not established any specific function for SEQ ID No. 5272. Further, there has been no specific use for SEQ ID NO. 5272, The specification asserts the claimed nucleic acids can be used to determine transcriptional profiling to find, identify, and characterize counterpart gene in other species (p. 2 lines 10-15). However, such uses lack a specific and substantial utility. Such uses allow only for the identification

and analysis of other nucleic acids. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for mapping studies, linkage analysis, constructing transgenic plants, and screening for traits or screening for polymorphisms (p. 2-3 and 17-18). However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID No. 5272 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and experimentation and do not provide a readily-available, specific and substantial real-world use.

The specification also suggests that the proteins encoded by the claimed nucleic acids could be used to generate antibodies, which could be used for detection purposes (p. 16-17). Again, because a utility has not been established for the nucleic acid or the protein encoded thereby, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for identifying markers and isolate promoters associated with proteins encoded by SEQ ID No. 5272 (15-16). The utility is not specific because it is a

property of all plant nucleic acids that they could be used to search for and try to identify a polymorphism or promoter. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. As stated in <u>Brenner v. Manson</u>, 383 U.S. 519, 148 USPQ 689 (1966), an invention does not have utility sufficient to satisfy §101 until it is "refined and developed" to the point of providing a specific benefit in currently available form. <u>Id</u> at 534-35, 148 USPQ at 695. In the instant application, Applicants have not set forth a single promoter or marker, which has been identified using the claimed SEQ ID NO: 5272.

All discussions regarding polymorphisms/markers in the specification are generic in nature. There is no showing of a reasonable expectation that the claimed nucleic acids could in fact be used to identify a specific promoter or marker. Even if a marker could be identified using the claimed SEQ ID NO: 5272, the specification has not disclosed a specific and substantial use for such an uncharacterized marker. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 5272 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use — e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of plant. Therefore, the nucleic acids of SEQ ID NO: 5272 may only be used to search for polymorphisms and if such polymorphisms are

identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

The specification asserts that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarray as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined.

The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 5272 or a protein encoded by SEQ ID NO: 5272 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid.

The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley (p. 21) is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement as it applies to nucleic acids. See <a href="In re Fisher">In re Fisher</a> 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Court held that 35 USC 101 requires a showing that a nucleic acid is both substantial and specific, stating that "not every 'use' that can be asserted will be sufficient to satisfy §101. "The court emphasized that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." <a href="Id.">Id.</a> 76 USPQ2d at 1230.

The <u>Fisher</u> Court also held that none of the uses asserted by Applicants in that case were either substantial or specific because each of the "asserted uses represent

merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." The Court concluded that "granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility."

The instant situation is analogous to that which was addressed in <u>Fisher</u>. In the present case, Applicants have not established that the claimed nucleic acid encodes for a protein with a specific and substantial biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism or promoter of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

### **Response to Arguments**

The reply traverses the rejection. A summary of the arguments presented in the reply are set forth below with response to arguments following.

(A) The reply asserts that the identified sequences can act as regulatory elements and as genes (p. 15 1<sup>st</sup> paragraph). The reply asserts that the office must

accept these stated utilities in the absence of evidence or sound scientific reasoning to rebut the applicants' assertions (p. 15 1<sup>st</sup> paragraph).

These arguments have been fully reviewed but have not been found persuasive.

Although it is acknowledged that a specific utility must be accepted by the office in the absence of evidence or sound scientific reasoning to rebut, the use of a sequence as a regulatory element or as a gene is not a specific utility. The terms regulatory element and gene are generic in nature and there is no showing in the instant specification that the claimed nucleic acid could be used to identify a specific regulatory gene.

(B) The reply asserts that provision application 60/155422 identifies SEQ ID No. 5272 (referred to as SEQ ID No. 9911) as a COL2 gene (p. 15 1<sup>st</sup> paragraph). The reply asserts that at the time of the filed application those skilled in the art were aware that COL2 referred to a "CONSTNAS-like" gene and shows significant homology to CONSTANS (p. 15 2<sup>nd</sup> paragraph). The reply asserts that CONSTANS has been identified as a putative zinc finger transcription factor affecting growth (e.g. flowering) (p. 15 2<sup>nd</sup> paragraph and p. 17 1<sup>st</sup> full paragraph). Therefore the reply asserts that applicants had established a specific, substantial, and credible utilities for SEQ ID no. 5272 at the time of filing (p. 15 2<sup>nd</sup> paragraph).

These arguments have been fully reviewed but have not been found persuasive.

The priority document does not state that SEQ ID NO. 5272 (referred to as SEQ ID NO. 9911) is a COL2 gene, but rather that it shares 34 percent identity to COL2.

Although COL2 is referred to as "CONSTNAS-like" there is no art on the record that the same transcription factors affecting growth are identical to a "CONSTNAS-like" gene. Further the is no evidence on the record that a sequence which shares only a 34% identity to a CONSTNAS-like gene would have the utility of being a transcription factor affecting growth. Although there is shared homology there is no evidence that the sequence possesses the required structure to functionally have such a utility.

(C) The reply asserts that even though there is only a 34% identity to COL2, and alignment of G1988 and COL2 share greater than 44% homology at the protein level within the zinc finger domain (p. 15 last paragraph -16 1st paragraph). G1988 is a nucleotide sequence that differs by a single nucleotides form the corresponding region of SEQ ID no. 5272 and is presented in the post filed US patent publication 2008/0010703 (p. 16 1st paragraph).

These arguments have been fully reviewed but have not been found persuasive.

Again, as stated above, although there is homology there is no evidence that the sequence possesses the required structure to functionally affect growth as the zinc finger domain does for COL2. As such, the instant specification has not provided any disclosure of a specific, substantial, and credible utility.

(D) The reply asserts that since the filing of the application additional evidence further demonstrating that the specific and substantial utility of SEQ ID NO. 5272 has been provided in US patent publication 2008/0010703 (p. 16 2<sup>nd</sup> paragraph and p. 17 2<sup>nd</sup> full paragraph). The reply asserts that although there is a nucleotide difference

between SEQ ID No. 5272 and the G1988, the difference does not alter the encoded protein (p. 16 last paragraph). The reply asserts that G1988 has been demonstrated to increase yield in plants in field trials conducted in 3 different years (p. 16 last paragraph).

These arguments have been fully reviewed but have not been found persuasive.

It is noted that the applicant appears to be asserting that the claimed sequence has the utility of a zinc finger in the COL2 gene. Although as stated above, the examiner concludes that there is no support for such an asserted utility, even if there were, the post filing evidence presented does not further demonstrate such a utility. The evidence has not shown that the increase yield in plants with regard to the sequence of G1988 is correlative to the same functionality as of the zinc finger in the COL2 gene.

Further, the Court held that 35 USC 101 requires a showing that a nucleic acid is both substantial and specific, stating that "not every 'use' that can be asserted will be sufficient to satisfy §101. "The court emphasized that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id. 76 USPQ2d at 1230. As such the instant specification has not provided that the sequence of 5722 has the same functionality of a zinc finger in the COL2 gene at the time of filing.

## Claim Rejections - 35 USC § 112/Enablemenet

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 12-14, 19-21, 26, 60-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

### **Response to Arguments**

The reply traverses the rejection. A summary of the arguments presented in the reply is set forth below with response to arguments following.

The reply asserts that the enablement rejection has been overcome by the forgoing arguments regarding utility (p. 18 section V).

These arguments have been fully reviewed but have not been found persuasive.

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As indicated above, the instantly claimed invention still has not overcome the issues concerning specific and substantial utility and as such both the 35 USC 101 rejection and the 35 USC 112/Enablement rejections have been maintained.

### Conclusion

- 12. No claims are allowed.
- 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday-Friday 8AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/ Examiner, Art Unit 1634

/Sarae Bausch/ Primary Examiner, Art Unit 1634